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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,814	09/19/2002	Glen Patrick Martyn	GJE-6035	4398
23557 7590 01/08/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/08/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/913,814

Applicant(s)

MARTYN ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8,9 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8,9 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and remarks dated 10-13-06 is acknowledged.

Claims 1, 4-6, 8-9 and 11-13 are pending in the instant application.

Response to Arguments

Applicant's arguments filed 10-13-06 have been fully considered but they are not persuasive.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 102

1. Claims 1, 9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,824,938 to Koyama et al (Koyoma).

A complete text of the rejection under this statute can be found in the previous action.

RESPONSE: Applicants argue that Koyoma do not state that the composition is an intact single dosage as required by the amended claims and instead uses the product for intravenous or intramuscular injection or as a test reagent, suggesting the need to convert the product into a liquid before administering. Applicants' arguments are not persuasive because according to the instant invention the instant composition is obtained by freeze-drying a solution in a mould to form a desired shape. Koyoma precisely teaches the same method. Further, according to the instant disclosure as well as claims (claim 9), instant composition further comprises a therapeutic agent, in addition to the polymer, pullulan. Koyoma also teaches therapeutic agents such as TNF

Art Unit: 1615

and IFN. In addition, Koyoma teaches the composition not only for intramuscular, intravenous but also for tablets. Thus, even though the reference does not disclose “for oral and buccal administration”, which is an intended use and not a positive limitation, the composition of Koyoma is capable of being administered by the claimed route because Koyoma teaches a tablet form, which does not require the conversion of the freeze-dried product into a liquid form.

With respect to the argument regarding a “shaped body”, the arguments are not persuasive because instant claims do not state a particular shape, nor do they exclude the argued “abstract” shape. Thus, Koyoma et al anticipate instant claims.

2. Claims 1, 9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 53012417 (JP).

A complete text of the rejection under this statute can be found in the previous action.

RESPONSE: Applicants argue that JP does not teach that its composition is an intact single dosage form and only teaches how to prepare the drugs without any reference to whether the listed steps are complete or how the product of the listed steps would be used. It is argued JP fails to teach that its composition is for oral or buccal administration and is ambiguous on how the drugs should be administered.

Applicants’ arguments are not persuasive because the abstract of JP, though short, is very clear in that it states, indomethacin (drug) is dissolved in water and pullulan. The very next sentence or statement that the solution was freeze-dried implies that the

Art Unit: 1615

product is complete at that stage and the process involves only the steps listed in the abstract. With respect to the argument regarding "for oral or buccal administration", the limitation is an intended use and does not patentable weight. Further, the composition of JP comprises the drug indomethacin, which is capable of being administered orally. Hence JP anticipates instant claims. With respect to the argument regarding the shaped body, JP does teach freeze-drying the product and the very process results in a solid shaped product. As explained in the preceding paragraphs, instant claims do not specify any shape and applicants themselves admit that freeze-drying can be carried out in any container of any shape, which is inclusive in the instant claims.

Claim Rejections - 35 USC § 103

3. Claims 4-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,824,938 to Koyoma et al (Koyoma).

A complete text of the rejection under this statute can be found in the previous action.

RESPONSE: Applicants argue that Koyoma suggest s different additives than those claimed in the instant application. It is argued that the internal or external treatments or tablets contemplated by Koyoma are compositions that do not include pullulan and those that include pullulan are for test reagents, or for injection. Applicants' arguments are not persuasive because Koyoma teaches that the dry solid composition is prepared by freeze-drying and the suggested forms include for internal and external treatment (abstract and col. 6, L30- 33). With respect to the argument regarding the coloring and

flavoring excipients of claim 6, Koyoma does not teach the claimed excipients.

However, Koyoma suggests adding excipients before preparing the dry solid that can be used as a tablet or a test reagent or for injection. Thus, choosing an appropriate excipient (which is by definition not an active agent), without affecting the solubility or the efficacy of the final composition would have within the scope of a skilled artisan because it is conventional to include flavoring agents or coloring agents in tablet art improve the appearance and impart flavor to the dosage form.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM


Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615

December 29, 2006



LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER